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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,434	07/03/2003	Aleksandar Milosavljevic	GMX 071394	4478

7590 08/08/2007

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,434	MILOSAVLJEVIC ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007 and 14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-80* is/are pending in the application.

4a) Of the above claim(s) *74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-73 and 75-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Claims 61-80 are pending in the instant application. Claim 74 is withdrawn from prosecution. Claims 61-73 and 75-80 are currently under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 09/632,539 and provisional Application No. 60/161,694, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 61 recites the limitation "fibrous DNA-immobilizing media" in lines 5, 12, and 13 of said claim. Claim 72 recites the limitation "fibrous DNA-immobilizing media" in lines 3-6 of said claim. Claim 78 recites the limitation "fibrous DNA-

immobilizing media" in lines 7, 8, 14, and 15 of said claim. Upon review, prior-filed Application No. 09/632,539 discloses DNA samples in a DNA repository stored in cards (see the specification of Application No. 09/632,539, page 27, lines 7-9). Further, provisional Application No. 60/161,694 discloses a DNA paper slide that accommodates an amount of blood or another biological sample (see the specification of Application No. 60/161,694, page 3, lines 6-8). However, the teachings of DNA stored on cards (see Appl. No. 09/632,539) and DNA paper slide that accommodates an amount of blood or another biological sample (see provisional Appl. 60/161,694) is narrower in scope than "fibrous DNA-immobilizing media" as recited in the instant claims. Therefore, the prior filed application fail to provide adequate support for fibrous DNA-immobilizing media as instantly claimed. Accordingly, applicants are not entitled to the benefit of the prior applications.

Drawings

The objection to the drawings in the instant application because of the additional reference character "5(a)", which did not appear in the Brief Description of the Drawings for figure 5 in the specification, has been withdrawn in view of amendments made to the instant application, filed 02/08/2007.

Specification

The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter is withdrawn in view of amendments made to the instant claims, filed 02/08/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims61-73 and 75-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by amendments made to the instant claims.

Claim 61 recites the limitation "fibrous DNA-immobilizing media" in lines 5, 12, and 13 of said claim. Claim 72 recites the limitation "fibrous DNA-immobilizing media" in lines 3-6 of said claim. Claim 78 recites the limitation "fibrous DNA-immobilizing media" in lines 7, 8, 14, and 15 of said claim. Upon review, the instant specification discloses DNA samples in a DNA repository stored in cards (see the specification, page 27, lines 7-9). However, the scope of the limitation "fibrous DNA-immobilizing media" is much broader than disclosed encompasses DNA repository stored in cards. Therefore, the

amendment to the instant claims to recite "fibrous DNA-immobilizing media" presents NEW MATTER that is not supported by the instant disclosure. Claims 62-71, 73, 75-77, 79, and 80 are also included under the instant rejection due to their dependence from claims 61, 72, and 78.

Claim Rejections - 35 USC § 102

The rejection of claims 61-73 and 75-80 under 35 U.S.C. 102(e)(2) as being anticipated by Hodge et al. (US Patent No. 6,977,178) is withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-73 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodge et al. (US Patent No. 6,977,178) in view of Burgoyne (US Patent No. 5,807,527). This rejection is necessitated by amendments made to the instant claims.

The instant claims are drawn to methods of providing selective biological samples from a sample archive comprising providing a sample repository of a plurality of samples derived from biological sources, wherein said samples are stored on fibrous DNA immobilizing media, providing an information database comprising medical history, clinical, or phenotypic information associated with said biological sources, determining a request from a sample selected from said plurality of samples, and removing at least a portion of said sample based upon said request.

Hodge et al. sets forth methods and related apparatuses for conducting transgenic and targeted mutagenesis screening of genomic DNA (see Hodge et al., Abstract). Hodge et al. discloses that the methods and systems includes a computer having a processor, memory and web browser, wherein the computer receives instructions concerning the designated genetic sequence and other screening parameter selection from a remote user via a form of electronic communication, and an automatic screening device that analyzes samples of genomic DNA for the designated sequence (see Hodge et al., Abstract and Figures 1 and 2). Hodge further discloses that one object of the disclosed methodology involves depositing prokaryotic or eukaryotic

genomic DNA on a substrate and detecting the genomic DNA with a microarray imager to facilitate high volume screening (see Hodge et al., col. 2, line 57 through col. 3, line 15). Additionally, the disclosed methodology comprises an order process that provides a remote user's selection parameters to conduct screening of a sample and provides the associated reagents, in a coordinated way facilitates high volume screening of transgenic and targeted mutagenesis samples for a designated genetic sequence. In addition, Hodge et al. further sets forth that the disclosed methodology is directed to the screening of genomic DNA from cellular lysate using magnetic particles and lysing the tissue sample with a lysis buffer that is formulated to work while the samples are in transit to the screening laboratory from a remote user.

Hodge et al. sets forth the use of an array station and an optical standardization technique wherein genomic DNA is deposited on the surface of a wells on a substrate (see Hodge et al. col. 20, line 48 through col. 21, line 47). The disclosed array station includes software that tracks the location of specific sample its particular position in an array. Hodge further set forth that the optical standardization station performs adjustments based on known sample volumes in secondary master well plates with the known DNA concentration to calculate the volume to hydrate or the time to desiccate each sample (see col. 21, lines 1-15). Hodge et al. further discloses exemplary embodiments wherein information regarding clinical and phenotypic information regarding requested samples is ascertained, recorded and included with test results (see Examples 1-4 of Hodge et al., col. 29, line 65 through col. 35, line 58). Example 1 demonstrates that a information regarding the nature of a control, specifically zygosity

and copy number, is provided (see Hodge et al., col. 30, lines 38-50). Example 4 further demonstrates the use of sample amplification using PCR (see col. 33, line 36 through col. 34, line 37). Hodge et al. further sets forth that screening methods may be used wherein at least one labeled target binding probe and at least one labeled reference binding probe is provided (see Hodge et al., col. 4, lines 35-60).

While Hodge et al. sets forth methods and related apparatuses for conducting transgenic and targeted mutagenesis screening of genomic DNA and the immobilization of DNA on a substrate, Hodge et al. does not fairly teach or suggest a fibrous DNA-immobilizing substrate as instantly claimed.

Burgoyne discloses a solid medium for use in the storage of DNA and DNA containing biological samples (e.g. blood) and methods involving the recovery or use of said DNA stored on a solid medium (See Burgoyne, Abstract and col. 1, lines 10-18). Burgoyne further discloses an exemplary embodiment wherein DNA is stored on cards made of absorbent paper (see Burgoyne, col. 4, lines 61 through col. 6, line 18), which reads on the newly presented limitation of a fibrous DNA-immobilizing media.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to use the solid DNA storage medium, as taught by Burgoyne, as the substrate used in the methods and related apparatuses for conducting transgenic and targeted mutagenesis screening of genomic DNA as taught by Hodge et al., because Burgoyne et al. teaches that the disclosed solid media for storing DNA is inexpensive and resolves technical issues with storing and transporting DNA samples (see Burgoyne, col. 1, lines 33

through col. 2, line 14). One of ordinary skill in the art would have a reasonable expectation of success because Hodge et al. further teaches the disclosed method and apparatus for of a plurality of conducting transgenic and targeted mutagenesis screening of genomic DNA accommodates a plurality of different DNA immobilizing substrates (see Hodge et al., col. 21, lines 17-32).

Response to Arguments

Applicant's arguments filed 02/08/2007 have been fully considered but they are not persuasive.

Regarding applicants claim of priority to Application No. 09/632,539 and provisional Application No. 60/161,694, applicants argue that the teaching and plain meaning of "paper" in the provisional application includes the instantly claimed limitation "fibrous DNA-immobilizing media".

In response, it is agreed that the teaching of paper as a DNA immobilizing media is encompassed by the newly recited limitation "fibrous DNA-immobilizing media". However, the scope of "fibrous DNA-immobilizing media" encompasses a broad range of embodiments outside of "paper" and, further, neither the instant disclosure nor the disclosures of Application No. 09/632,539 and provisional Application No. 60/161,694 provides support for the additional subject matter encompassed by the newly presented limitation of "fibrous DNA-immobilizing media".

Regarding the prior art of Hodge et al. al, applicants argue that reference fails to suggest an automated archive repository combining corresponding medical information for archival samples.

Applicants argument is not persuasive. The computer assisted methods and related apparatuses for conducting transgenic and targeted mutagenesis screening of genomic DNA disclosed by Hodge et al. requires the storage of DNA on a DNA immobilizing substrates, which reads on an automated archive repository system. Hodge et al. further discloses exemplary embodiments wherein information regarding clinical and phenotypic information regarding requested samples is ascertained, recorded and included with test results (see Examples 1-4 of Hodge et al., col. 29, line 65 through col. 35, line 58), which reads on the recitation of phenotypic information associated with biological sources corresponding to said plurality of samples (see lines 7-9 of claim 61).

Applicant's arguments that Hodge et al. fails to reach fibrous DNA-immobilizing media has been considered but are moot in view of the new grounds of rejection under 35 USC 103(a) as being unpatentable over Hodge et al. in view of Burgoyne et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER